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| EXAMINER | |
|---|---|
| ROONEY, NORA MAUREEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

| NOTIFICATION DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/554,409 | GRONLUND ET AL. | |
| | Examiner | Art Unit | |
| | NORA ROONEY | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

5)☒ Claim(s) *22,28,33-40 and 42-47* is/are pending in the application.

5a) Of the above claim(s) *34-36,39 and 40* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *22,28,33,37,38 and 42-47* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

10)☒ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/23/2011 has been entered.

2. Claims 22, 28, 33-40, 42-47 are pending.

3. Claims 34-36 and 39-40 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/16/2010.

4. Claims 22, 28, 33, 37-38 and 42-47 are currently under consideration as they read on a recombinant Fel d 1 fusion product comprising a Fel d 1 chain 1 and a Fel d 1 chain 2 linked by carbon-nitrogen bond wherein the N- terminal amino acid of chain 1 is lined to the C-terminal amino acid of claim 2, pharmaceutical compositions and kits thereof.

***Specification***

5. The disclosure is objected to because of the following informalities:

SEQ ID NO:4 and SEQ ID NO:35 are 100% identical sequences. The sequence of Figure 1 is referred to on page 3, lines 18-19 as SEQ ID NO:35, but it is also SEQ ID NO:4. Applicant is required to correct this discrepancy in the sequence listing, CRF and specification. It is inappropriate to list the same sequence with two sequence identification numbers.

Appropriate correction is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 22, 28, 33, 37-38, and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites 'variants' to SEQ ID NOs 1 and 2 comprising specified mutations. However, the claimed variants of SEQ ID NOs 1 and 2 encompass any variant that has the specified mutations including polypeptides of no relation to SEQ ID NOs 1 and 2 so long as they are encompassed by the term "variant" as defined by the specification. However, the claims still do read on any variant since Applicant did not limit the claims to 'consisting of' language. The 'variants' may comprise any number of additional amino acid changes in addition to the ones listed. Furthermore, the comprising language makes it possible to add any number of additional amino acids on the N- and/or C-terminus of the fusion protein, as evidenced by claims 42-45. It is not disclosed in the specification: 1.) what polypeptide lengths of the recited sequences would qualify as a variant; 2.) what portions of the recited sequences are essential to qualify as variants; 3.) what amino acids can be changed and to what amino acids and still be a variant; and 4.) what

sequences can be added to the sequences and still be encompassed by the term variant. Without a limiting definition in the specification, the term variant is indefinite.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 22, 28, 33, 37-38 and 42-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: the polypeptides of SEQ ID NO: 1, 2, 3 and fusions thereof (including SEQ ID NO:4/35) and compositions and kits thereof, does not reasonably provide enablement for: **a recombinant Fel d 1 fusion product** comprising a Fel d 1 chain 1 and a Fel d 1 chain 2, wherein the Fel d 1 chain 1 **comprises** the amino acid sequence set forth in SEQ ID NO: 1 or **a variant of the amino acid sequence set forth in SEQ ID NO: 1**, wherein Fel d 1 chain 2 **comprises** (i) the amino acid sequence set forth in SEQ ID NO: 2 or **a variant of the amino acid sequence set forth in SEQ ID NO: 2** or (ii) the amino acid sequence set forth in SEQ ID NO: 3, wherein the N-terminus of the Fel d 1 chain 1 is in peptide linkage with the C-terminus of the Fel d 1 chain 2, wherein the variant of the amino acid sequence set forth in SEQ ID NO:1 is selected from the group consisting of SEQ ID NO: 1 having Lys29Arg, SEQ ID NO: 1 having Lys 29Asn and SEQ ID NO: 1 having Va133Ser, and wherein the variant of the amino acid sequence set forth in SEQ ID NO:2 is selected from the group consisting of SEQ ID NO:2 having Asn19Ser, SEQ ID NO:2 having Gly20 Leu, SEQ ID NO:2 having Ile55Val, SEQ ID NO:2 having Arg57Lys, SEQ ID NO:2 having Va158Phe, SEQ ID NO:2 having Glu69Val, SEQ ID NO:2 having Tyr72Asp, SEQ ID NO:2 having GIn79Glu and SEQ ID

NO:2 having Asn88Lys of claim 22; wherein the chain 1 and the chain 2 are covalently bonded together by one or more disulfide bridges into an antiparallel arrangement of claim 28; **a homodimer** consisting of two non-covalently associated **fusion products** as claimed in claim 22 of claim 33; a **pharmaceutical composition** comprising an immunotherapeutically effective amount of **the fusion product** as claimed in claim 22 and/or **the homodimer** as claimed in claim 33 and a pharmaceutically acceptable carrier, excipient or diluent of claim 37; **a kit for the diagnosis of cat allergy comprising the fusion product** as claimed in claim 22 and/or **the homodimer** as claimed in claim 33 and instructions for use of the kit of claim 38; wherein the Fel d 1 chain 2 further has a methionine residue on the N-terminus of claim 42; wherein the Fel d 1 chain 1 further has the sequence Leu-Glu-(His)6 on the C-terminus of claim 43; wherein the Fel d 1 chain 1 further has the sequence Leu-Glu-(His)6 on the C-terminus of claim 44; wherein the fusion product has the amino acid sequence set forth in SEQ ID NO: 4 of claim 45; a **pharmaceutical composition** comprising an immunotherapeutically effective amount of **the fusion product as claimed in claim 45** and a pharmaceutically acceptable carrier, excipient or diluent of claim 46; and **a kit for the diagnosis of cat allergy comprising the fusion product** as claimed in claim 45 and instructions for use of the kit of claim 46.

Applicant's argument filed on 08/01/2011 has been fully considered, but is not founr persuasive.

Applicant argues:

> 'It is not clear to Applicants how a claim to a variant of SEQ ID NO: 1, for example, could read on numerous polypeptides that are completely unrelated to SEQ ID NO: 1. The Examiner also argues that claim 22 uses open language and therefore read on "polypeptide variants having any number of mutations in addition to the ones listed in claim 22." Again, Applicants do not understand the Examiner's argument.

The mutations that are permissible in the claimed polypeptide variants are specified in two Markush groups in claim 22, and are thus described with closed language ("selected from the group consisting of). Thus, one of skill in the art would understand that the only mutations that are permissible in the claimed variants are those that are enumerated in the Markush groups. The open language ("comprising") does not modify the enumerated mutations. Thus, an embodiment of claim 22 can be construed (as to SEQ ID NOs 1 and 2) to read on fusion products that comprise SEQ ID NO: 1 or an enumerated variant thereof, together with SEQ ID NO: 2, or an enumerated variant thereof, linked together with a specific peptide linkage. In addition and solely in the interest of expediting prosecution, Applicants have amended the language of claim 22, as discussed above, to clarify that the variants are with respect to the identified SEQ ID NO, e.g., SEQ ID NO: 1 having Lys29Arg. Furthermore, while the open transitional language permits the fusion product to have polypeptide sequences in addition to the claimed sequences, it does not permit the claimed fusion product to be a polypeptide that is completely unrelated to SEQ ID NOs 1 and 2, nor does it permit mutations in addition to those enumerated in the claims (because of the closed Markush language).

In addition to the issue regarding claim construction, discussed above, Applicants also note that the Examiner states that undue experimentation would be required to provide a pharmaceutical formulation to administer the protein. Applicants traverse.

The Examiner accepts that the skilled person can prepare the heterodimer of the present invention based on the detailed description and examples. Once formed, it would be part of the routine common general knowledge of the skilled person to formulate a protein for administration. In this regard, it should be noted that vaccines for human use have been known for many years prior to the filing of the present application, and techniques for formulating vaccines for injection are well established.

Another common protein-containing pharmaceutical product is based on human or humanized monoclonal antibodies. This is a multi-billion dollar industry and the techniques for formulating the products are well known. Examples include anti-TNF alpha, Omalizumab® (a recombinant DNA-derived humanized IgG1 k monoclonal antibody for treating allergic asthma) and Cetuximab® (a chimeric monoclonal antibody
for the treatment of certain cancers).

It is not an exaggeration to say that, at the filing date of the present application, all major pharmaceuticals companies world-wide had some focus on products incorporating proteins and the techniques for formulating them were available.

To provide specific examples, a commonplace approach to induce immunogenicity of a protein is to adsorb the protein to carrier substances prior to injection. Aluminum hydroxide, aluminum phosphate or tyrosin are such "classical" carrier substances which are used for vaccines and other proteins in order to induce an immune response after injections. This is a very simple and straight forward approach. Indeed, suitable carriers were commercially available at the filing date of the present application, for example Alhydrogel® from Brenntag, Denmark, which is an aluminum hydroxide carrier specifically intended for protein-containing pharmaceutical formulations. To prepare the formulation, the protein in a buffer (which stabilizes the protein in a refolded state) is simply combined with the carrier. Therefore, the skilled person could prepare a suitable formulation based on his common general knowledge using commercially available materials without an undue burden. Accordingly, this rejection should be withdrawn."

The terms 'variant,' 'comprising ' and 'having' are open language. As written, the claims encompass an enormous number of undisclosed polypeptide variants that may include sequence

that is unrelated to the polypeptides of SEQ ID NO:1 and 2, as evidenced by claims 42-45. Claim 22 recites mutations to SEQ ID NOs 1 and 2. However, as recited, the claims still read on polypeptide variants having any number of mutations in addition to the ones listed in claim 22. Contrary to Applicant's assertion, there is no limiting definition of variants in the specification and the claims do encompass variants having any number of additional mutations within SEQ ID NO's 1-3. In order to perform as a pharmaceutical the composition must have pharmaceutical use. The ability to be injected or formulated with a carrier is not a pharmaceutical use. The claims must be directed to a limited genus of fusion proteins with pharmaceutical use as disclosed in the specification. Applicant's arguments regarding vaccines, proteins and antibodies for pharmaceutical use have no bearing on this rejection which is limited to the claimed fusion proteins and the pharmaceutical use thereof. See MPEP 2164.01 (c)

It remains the Examiner's position that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 22 recites mutations to SEQ ID NOs 1 and 2. However, as recited, the claims read on polypeptide variants having any number of mutations in addition to the ones listed in claim 22. The terms 'comprising ' and 'having' are open language. As written, the claims encompasses an enormous number of undisclosed polypeptide variants that may include sequence that is unrelated to the polypeptides of SEQ ID NO:1 and 2. It is suggested that Applicant amend the claims to recite that the variants consist of SEQ ID NOs 1 or 2 with the recited mutations.

Absent a limiting definition in the specification, the recited fusion comprises comprising the recited polypeptide 'variants' reads on all polypeptides which comprise those specific mutations. There is insufficient guidance in the specification as filed as to how the skilled artisan would make the various variants recited in the instant claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences of a polypeptide variant that is encompassed by the instant claim recitation. There is insufficient guidance to direct a person of skill in the art to select particular sequences or sequence lengths as essential for the claimed functions. Without detailed direction as to which sequences are essential to the function of the encoded polypeptide, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of protein and peptide sequences encompassed by the instant claims would exhibit the claimed functional characteristics and which can be used in a pharmaceutical composition.

Also at issue is whether or not the genus of claimed compositions, including the fusion protein of SEQ ID NO:4/35, that would function in vivo as pharmaceutical compositions which can be used on or in the body to alleviate, treat or cure a disease in humans or animals. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical compositions are effective for in vivo use, and the lack of predictability in the art at the time the invention was

made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Further, given the broad genus of fusion proteins encompassed by the instant claim recitations, it would be unpredictable to use a fusion protein encompassed by the instant claim recitations in a kit for diagnosis of cat allergies. Cat allergy diagnosis would presumably be performed by using the fusion protein to determine whether or not a patient has Fel d 1 specific IgE antibodies or T cells by performing in vivo or in vitro experiments with the fusion protein. However, since the fusion proteins encompassed by the instant claim invention may comprise sequences with little to no homology to Fel d 1, it is unpredictable whether those fusion proteins can be used to diagnose allergies to cats. For example, a Fel d 1 fusion protein with undisclosed sequence or sequence variation can bind to antibodies that are not specific for Fel d 1 or cats at all. Therefore, one of ordinary skill in the art would be required to perform undue experimentation to practice the invention commensurate in scope with the claims.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the changes which can be made in the instantly recited polypeptide that maintains the functional properties of the polypeptides of SEQ ID NOs 1 and 2 is unpredictable, as is the identity of which subsequences would encode a functional polypeptide; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

10. Claims 22, 28, 33, 37-38 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : polypeptides of SEQ ID NO:1, 2 or 3 and fusions thereof (including SEQ ID NO:4/35) and compositions and kits thereof

Applicant is not in possession of : **a recombinant Fel d 1 fusion product** comprising a Fel d 1 chain 1 and a Fel d 1 chain 2, wherein the Fel d 1 chain 1 **comprises** the amino acid sequence set forth in SEQ ID NO: 1 or **a variant of the amino acid sequence set forth in SEQ ID NO: 1**, wherein Fel d 1 chain 2 **comprises** (i) the amino acid sequence set forth in SEQ ID NO: 2 or **a variant of the amino acid sequence set forth in SEQ ID NO: 2** or (ii) the amino acid sequence set forth in SEQ ID NO: 3, wherein the N-terminus of the Fel d 1 chain 1 is in peptide linkage with the C-terminus of the Fel d 1 chain 2, wherein the variant of the amino acid sequence set forth in SEQ ID NO:1 is selected from the group consisting of SEQ ID NO: 1 having Lys29Arg, SEQ ID NO: 1 having Lys 29Asn and SEQ ID NO: 1 having Va133Ser, and wherein the variant of the amino acid sequence set forth in SEQ ID NO:2 is selected from the group consisting of SEQ ID NO:2 having Asn19Ser, SEQ ID NO:2 having Gly20 Leu, SEQ ID NO:2 having Ile55Val, SEQ ID NO:2 having Arg57Lys, SEQ ID NO:2 having Va158Phe, SEQ ID NO:2 having Glu69Val, SEQ ID NO:2 having Tyr72Asp, SEQ ID NO:2 having GIn79Glu and SEQ ID NO:2 having Asn88Lys of claim 22; wherein the chain 1 and the chain 2 are

covalently bonded together by one or more disulfide bridges into an antiparallel arrangement of claim 28; **a homodimer** consisting of two non-covalently associated **fusion products** as claimed in claim 22 of claim 33; a pharmaceutical composition comprising an immunotherapeutically effective amount of **the fusion product** as claimed in claim 22 and/or **the homodimer** as claimed in claim 33 and a pharmaceutically acceptable carrier, excipient or diluent of claim 37; **a kit for the diagnosis of cat allergy comprising the fusion product** as claimed in claim 22 and/or **the homodimer** as claimed in claim 33 and instructions for use of the kit of claim 38; wherein the Fel d 1 chain 2 further has a methionine residue on the N-terminus of claim 42; wherein the Fel d 1 chain 1 further has the sequence Leu-Glu-(His)6 on the C-terminus of claim 43; wherein the Fel d 1 chain 1 further has the sequence Leu-Glu-(His)6 on the C-terminus of claim 44; wherein the fusion product has the amino acid sequence set forth in SEQ ID NO: 4 of claim 45; a pharmaceutical composition comprising an immunotherapeutically effective amount of **the fusion product as claimed in claim 45** and a pharmaceutically acceptable carrier, excipient or diluent of claim 46; and **a kit for the diagnosis of cat allergy comprising the fusion**

**product** as claimed in claim 45 and instructions for use of the kit of claim 46.

Applicant's argument filed on 08/01/2011 has been fully considered, but is not founr persuasive.

Applicant argues:

> "The Examiner has also rejected claims 22, 28, 33, 37-38 and 42-47 under 35 USC § 112, first paragraph, for a lack of written description. This rejection also seems to relate to the claim construction issue discussed above in conjunction with the enablement rejection. Those claim construction arguments also apply to and obviate this rejection. Accordingly, this rejection should be withdrawn."

The terms 'variant,' 'comprising' and 'having' are open language. As written, the claims encompass an enormous number of undisclosed polypeptide variants that may include sequence that is unrelated to the polypeptides of SEQ ID NO:1 and 2, as evidenced by claims 42-45. Claim 22 recites mutations to SEQ ID NOs 1 and 2. However, as recited, the claims still read on polypeptide variants having any number of mutations in addition to the ones listed in claim 22. Contrary to Applicant's assertion, there is no limiting definition of variants in the specification and the claims do encompass variants having any number of additional mutations within SEQ ID NO's 1-3.

It remains the Examiner's position that the 'variant' "comprising" and 'having' language of claim 22 combined with the term variant reads on a genus of variants that have not been adequately described in the specification. The recited polypeptide variants may comprise any number of additional mutations to SEQ ID NOs 1 and 2, so long as they comprise the recited mutations. Essentially, the recited mutations are the only necessary structure for the recited variants because they may encompass any number of further mutations, deletions and additions. The specification has not adequately described a genus of such variants that can be used for the disclosed diagnostic and pharmaceutical use.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 22 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,048,962 (PTO-892 mailed on 04/01/2011; Reference A).

Applicant's arguments filed on 08/01/2011 have been fully considered, but are not found persuasive.

Applicant argues:

> "Even assuming arguendo that Gefter discloses SEQ ID NOs 1 and 2 of the present application (see SEQ ID NOs 2 and 6, respectively, in US 6,048,962), the Gefter sequences are not brought together and they are certainly not linked with a carbon-nitrogen bond. The claims of the present application are therefore novel over Gefter, at least in view of the peptide linkage limitation of claim 22."

At the outset, it is noted that reference SEQ ID NO:2 comprises 100% of SEQ ID NO:1 and reference SEQ ID NO:6 comprises 100% of SEQ ID NO:2. It is further noted that the sequences are linked (In particular, claim 12). The reference teaches that the covalent bonding of instant SEQ ID NOs 1 and 2 may be by the construction of gene chimeras, where chains 1 and 2, or parts thereof, may be linked to form a single contiguous chain where all or a portion of chain 1 may be linked with all or a portion of chain 2 cDNA and the resulting chimera may be produced as a recombinant hybrid (In particular, column 16, lines 56-65). Therefore, reference SEQ ID NOs 2 and 6 are in fact taught to be linked with a peptide bond.

U.S. Patent 6,048,962 teaches the Fel d 1 allergen comprising chain 1 of reference SEQ ID NO:2 (comprising instant SEQ ID NO:1) and chain 2 of reference SEQ ID NO:6 (comprising SEQ ID NO:2) covalently bonded and a kit thereof with instructions for use. (In particular, claims 12-19, column 25, lines 60-62, whole document).

The reference teachings anticipate the claimed invention.

13. Claims 22 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2002/0164342 (PTO-892; Reference A).

U.S. Patent Application Publication 2002/0164342 teaches a composition comprising a baculovirus expressed recombinant Fel dI comprising chain 1 of SEQ ID NO:1 and chain 2 of SEQ ID NO:2 expressed in series and linked together by a glycine/serine linker (In particular, claims 1-2, whole document).

It is noted that "chain 1" comprising SEQ ID NO:1 and "chain 2" comprising SEQ ID NO:2 of the fusion protein of claim 22 may each include additional amino acids. Therefore, the glycine and serine linker is included in "chain 1" or "chain 2." Alternatively, "chain 1" includes a serine and "chain 2" includes a glycine. Chain 1 and Chain 2 are therefore in direct peptide linkage.

The reference teachings anticipate the claimed invention.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-

0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 27, 2011

/Nora M Rooney/

Examiner, Art Unit 1644